K063170

JAN 12 2007

CONFIDENTIAL

XI. 510(k) Summary

Submitter: Mr. Eugenio Miceli, QA Manager, Micerium SpA, Via Marconi, 83, 16030 Avegno (GE), Italy. Phone: 39 0185 7885 880.

I. Classification Name and Number:
Resin, denture, relining, repairing, rebasing - 872.3760 (Product Code 76EBI) .
Class: II

II. Common/Usual Name:
Fiber reinforcement material

III. Proprietary Name:
Tender Fiber Ortho, Tender Fiber Due, Tender Fiber Quattro.

IV. Registration No.:
Foreign, in process

V. Compliance with Performance Standards:
"ISO 4049:2000 Dentistry – Polymer – Based Filling, Restorative and Luting materials".

"ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes"

For the Citotoxicity tests:
"ISO 10993 -I:2003--Evaluation and testing"
"ISO 10993 -5:1999--Tests for in vitro citotoxicity"
"ISO 10993-I2:2002-- Sample preparation and reference materials"

For risk analysis
"ISO 14971:2000/Amd 1:2003 – MEDICAL DEVICES – Application of risk management to medical devices"

VI. Premarket Notification truthful and accurate statement

VII. Description of the Device:
Tender Fiber are silanized glass fibers, impregnated with light curing resin used to reinforce prosthodontic appliances and to repair or reinforce denture and orthodontic appliances.

VIII. Labels and Labeling: Draft labels of the Tender Fiber and instructions for use are provided.

IX. Substantial Equivalence:

The Tender fiber are substantially equivalent to:

- Everstick by Stick Tech Ltd., 510 (k) no.: K011788
- Everstick Perio by Stick Tech Ltd., 510 (k) no.: K030072
- Everstick Ortho by Stick Tech Ltd., 510 (k) no.: K021126
- Stick by Stick Tech Ltd., 510(k) no.: K003333
- Ribbond (TM) by Ribbond Inc, 510(k) no.: K913040

1. These products have the same intended use as predicate devices.

2. Technological characteristics: Ribbond an ultra high modulus polyethylene fiber ribbon with no impregnation, while Stick is a polymer pre-impregnated unidirectional continuous glass fiber.

Everstick, Everstick Perio, Everstick Ortho and Tender fiber have the same technological characteristics of Stick but they are also impregnated with light curing resin.Curing is made with help of dental halogen, plasma or LED light systems. The curing process is triggered by initiators, which initiate the polymerization. These initiators are activated by certain wavelengths of the different light systems and are similar or exactly the same in all listed materials.

Test results indicate that there are no hazards presented with the use of Tender Fiber as compared with the predicate devices. The different technological characteristics of Tender Fiber (practically the same of Everstick, Everstick Perio, Everstick Ortho) compared with Stick and Ribbond does not raise new questions of safety and effectiveness and demonstrates that the device is safe and effective as the predicate devices.

IX.1 Risk to Health.

Potential adverse affects and complications common to glass fibers impregnated with a light curing resin include:

- Allergies or hypersensivities
- No adhesion or incomplete adhesion to teeth
- incorrect or incomplete curing

Cytotoxicity tests appears in appendix II.1

X. Indications for Use.

Tender fiber is a semi-manufactured product made of fibers used to reinforce composite and acrylic prosthodontic appliances and to repair or reinforce denture and orthodontic appliances. It can be use as well to immobilize teeth for periodontal or orthodontic treatments.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Eugenio Miceli
Quality Assurance Manager
Micerium S.P.A.
Via Marconi 83
Avegno, Italy 16030

JAN 12 2007

Re: K063170
Trade/Device Name: Tender Fiber
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: October 12, 2006
Received: October 18, 2006

Dear Mr. Miceli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

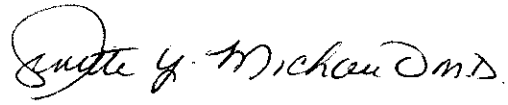
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. Indications for Use [Separate Page]

510(k) Number: (not assigned) K063170

Device Name: Tender Fiber

Indications for Use: Tender fiber is a semi-manufactured product made of fibers used to reinforce composite and acrylic prosthodontic appliances and to repair or reinforce denture and orthodontic appliances. It can be use as well to immobilize teeth for periodontic or orthodontic treatments.

These products are for use only by trained and experienced dentists and dental technicians and have become well-known in this area of dentistry, therefore they do not require prescription (Per 21 CFR 801 Subpart D)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K063170

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)